



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Depuy (Ireland)
Ms. Rhonda Myer
Senior Regulatory Affairs Associate
Loughbeg Ringaskiddy
Co. Cork,
IRELAND

Re: K101996

Trade/Device Name: DePuy Global UNITE Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, MBF, KWS, HSD
Dated: November 23, 2010
Received: November 24, 2010

Dear Ms. Myer:

This letter corrects our substantially equivalent letter of December 15, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K101996

Section 4: Indications for Use Statement

510 (k) Number (if known): K101996

Device Name: DePuy Global UNITE Shoulder System

Indications for Use:

The Global UNITE humeral stems, suture collars, epiphyseal components and humeral heads are intended for cemented or uncemented total shoulder or hemi-shoulder replacement in treatment of the following:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component)

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures
2. Avascular necrosis of the humeral head
3. Deformity and/or limited motion

When used in a total shoulder replacement, the Global UNITE implants are to be used with DePuy glenoids. The glenoids are for cemented use only.

When well-fixed, the Global UNITE humeral stems, in conjunction with existing Delta Xtend epiphyseal components, are also indicated for conversion to a reverse, in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary. The Delta Xtend metaglene component is HA-coated and is intended for uncemented use with the addition of screws for fixation. The Delta Xtend epiphyseal components are HA-coated and are intended for uncemented use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

K101996

K101996
p 1/3

Section 5: 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

DEC 15 2010

NAME OF SPONSOR: DePuy (Ireland)
Loughbeg
Ringaskiddy
Co. Cork Ireland
Establishment Registration Number: 9616671

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DATE PREPARED: December 15, 2010

PROPRIETARY NAME: DePuy Global UNITE Shoulder System

COMMON NAME: Total and Hemi Shoulder Arthroplasty Prosthesis

CLASSIFICATION AND REGULATION: Class II per 21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis (KWS)
Class II per 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (HSD)
Class II per 21 CFR 888.3670: Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis (MBF)

DEVICE PRODUCT CODE AND DESCRIPTION: KWS: Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
HSD: Prosthesis, Shoulder, Hemi-, humeral, Metallic Uncemented
MBF: Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Uncemented

PREDICATE DEVICES DePuy Global AP, K063652 (stem) and K060874 (head)
DePuy Delta Xtend, K071379

DEVICE DESCRIPTION:

The Global UNITE Shoulder System includes a two-piece stem design that provides the option to convert a primary fracture prosthesis to a reverse prosthesis, a suture collar, an epiphyseal component, and a humeral head. In the case of failed tuberosity healing, the surgeon will be able to remove the Global UNITE epiphyseal component and replace it with a Delta Xtend Reverse epiphyseal component without removing the well-fixed distal stem.

INDICATIONS AND INTENDED USE:**Indications:**

The Global UNITE humeral stems, suture collars, epiphyseal components and humeral heads are intended for cemented or uncemented total shoulder or hemi-shoulder replacement in treatment of the following:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component)

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures
2. Avascular necrosis of the humeral head
3. Deformity and/or limited motion

When used in a total shoulder replacement, the Global UNITE implants are to be used with DePuy glenoids. The glenoids are for cemented use only.

When well-fixed, the Global UNITE humeral stems, in conjunction with existing Delta Xtend epiphyseal components, are also indicated for conversion to a reverse, in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary. The Delta Xtend metaglene component is HA-coated and is intended for uncemented use with the addition of screws for fixation. The Delta Xtend epiphyseal components are HA-coated and are intended for uncemented use.

Intended Use:

The Global UNITE humeral stems, suture collars, epiphyseal components and humeral heads are intended for total shoulder or hemi-shoulder replacement.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on the similarities in intended use, indications for use, materials, and design, DePuy believes the subject Global UNITE Shoulder System is substantially equivalent to the previously cleared DePuy Global AP and Delta Xtend Shoulder Systems, cleared in K063652, K060874 and K071379.

Technological Characteristics

The technological characteristics of the DePuy Global UNITE Shoulder System are similar to the predicate devices, including geometry, design, size range, material, and porous coating. The differences include the following: The predicate Global AP only has suture holes on the stem, and the subject Global UNITE System has suture holes on the stem and also a suture collar for tuberosity reattachment. The predicate Global AP stem has a female taper with linking components that attach to the head while the subject Global UNITE has a male taper on the epiphyseal component that attaches to the head. The predicate Global AP does not have a modular epiphyseal component and the subject Global UNITE does have a modular epiphyseal component. The predicate Global AP heads have more material on the underside of the head than the Global UNITE heads. The predicate Delta Xtend does not have sizes 6 and 8 while the subject Global UNITE does offer sizes 6 and 8.

Performance Data

The Global UNITE Shoulder System was subjected to the following pre-clinical testing: Collar taper axial disassembly strength (ASTM F2009-00), Collar taper torque disassembly strength, Collar taper fatigue testing and axial disassembly strength, Humeral head taper axial disassembly strength (ASTM F2009-00), Anatomic configuration fatigue testing (ASTM 1378-05, and Reverse configuration fatigue testing (ASTM 1378-05).

Conclusion

DePuy believes the DePuy Global UNITE Shoulder System is substantially equivalent to the predicate devices, Global AP and Delta Xtend, as confirmed through device testing and validation activities. No new issues of safety and efficacy have been raised with the Global UNITE Shoulder System.